



U.S. FOOD & DRUG
ADMINISTRATION

July 29, 2022

Ellipse Technologies, Incorporated
John McIntyre
Vice President, Regulatory, Quality, and Clinical Affairs
13900 Alton Parkway
Suite 123
Irvine, California 92618

Re: K141278

Trade/Device Name: MAGEC® Spinal Bracing and Distraction System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGN

Dear John McIntyre:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 24, 2015. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 24, 2015

Ellipse Technologies, Incorporated
Mr. John McIntyre
Vice President, Regulatory, Quality and Clinical Affairs
13900 Alton Parkway, Suite 123
Irvine, California 92618

Re: K141278

Trade/Device Name: MAGEC® Spinal Bracing and Distraction System
Regulatory Class: Unclassified
Product Code: PGN
Dated: February 20, 2015
Received: February 23, 2015

Dear Mr. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement on last page.

510(k) Number (if known)

K141278

Device Name

MAGEC® Spinal Bracing and Distraction System

Indications for Use (Describe)

The Ellipse MAGEC Spinal Bracing and Distraction System is intended for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k) Summary
Ellipse MAGEC® Spinal Bracing and Distraction System
510(k) Summary – K141278
September 2014

- 1. Company:** Ellipse Technologies, Incorporated
13900 Alton Parkway, Suite 123
Irvine, CA 92618

Contact: John McIntyre
Vice President, RA/QA/CA
Phone: (949) 837-3600
Fax: (949) 837-3664

Date Prepared: September 26, 2014

FDA Establishment Registration No: 3006179046

- 2. Proprietary Trade Name:** MAGEC® Spinal Bracing and Distraction System
- 3. Common Name:** Non-Fusion Growing Rod
- 4. Classification Name:** Unclassified (Product Code PGN, Growing Rod System – Magnetic Actuation)
- 5. Predicate Device:** Ellipse Technologies, Inc. MAGEC® Spinal Bracing and Distraction System, K140178
- 6. Product Description:** The Ellipse Technologies, Inc. MAGEC Spinal Bracing and Distraction System is comprised of a sterile single use spinal rod that can be surgically implanted using appropriate Stryker® Xia® fixation components (i.e. Pedicle screws, hooks and/or connectors). The system includes a non-sterile hand held External Remote Controller (ERC) that is used at various times after implant to non-invasively lengthen or shorten the implanted spinal rod. The implanted spinal rod is used to brace the spine during growth to minimize the progression of scoliosis. The titanium rod includes an actuator portion that holds a small internal magnet. The magnet in the actuator can be

turned non-invasively by use of the ERC. Rotation of the magnet causes the MAGEC rod to be lengthened or shortened.

The hand held non-invasive ERC is electrically powered. The ERC is placed over the patient's spine and then manually activated, which causes the implanted magnet to rotate and either lengthen or shorten the rod. Periodic lengthening of the rod is performed to distract the spine and to provide adequate bracing during growth to minimize the progression of scoliosis. Once the physician determines that the implant has achieved its intended use and is no longer required, the implant is explanted. Additional accessories for the MAGEC System include the MAGEC Manual Distractor and the MAGEC Wand Magnet Locator. The MAGEC Manual Distractor is a sterilizable, single use device, which is used in the operating room to test the device prior to implantation. The MAGEC Wand Magnet Locator is a non-sterile device which is used during the distraction procedure to locate the magnet within the MAGEC rod. The ERC is placed over this location on the child's back during a distraction procedure.

7. Indications for Use: The Ellipse MAGEC Spinal Bracing and Distraction System is intended for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth.

8. Substantial Equivalence: Documentation demonstrates substantial equivalence to the Ellipse MAGEC System cleared under K140178 (cleared on February 27, 2014). The purpose of this premarket notification is to include a second generation External Remote Controller (ERC 2) into the System. Data provided in this submission includes information relevant to the ERC 2. Substantial equivalence is based on similar indications for use, designs, *in vitro* testing and software validation. The *in vitro* evaluations included specific tests performed on the ERC 2 to demonstrate the suitability of the device for its intended use, and electrical safety and electromagnetic compatibility tests.

9. Technological Characteristics: The ERC 2 was designed to improve ergonomic handling and user interfaces, and has the same methods and principles of operation as the first generation ERC. The ERC 2 incorporates the controller and hand piece into one unit, to be more ergonomic and user friendly. The ERC 2 contains a colored touchscreen LCD-display screen. The second generation ERC for the Ellipse MAGEC System was developed and evaluated in accordance with recognized standards and with in-house developed test methodologies. This testing includes risk assessment of the device and testing to applicable IEC standards, which are included in this premarket notification. The results of testing demonstrate that the ERC 2 for the Ellipse MAGEC System that is the subject of this premarket

notification is substantially equivalent to the predicate ERC cleared in the original premarket notification, K140178.

10. Non-Clinical Performance Data: Non-clinical testing on the MAGEC System includes design functionality and verification on the ERC 2 device. The following documentation and testing have been included in order to establish equivalence to the predicate device.

Test/Document Description	Applicable test standard
Risk Management Report	EN ISO 14971
Electrical Safety	IEC 60601-1 (3 rd edition)
Electromagnetic Compatibility and Interference	IEC 60601-1-2
Design Verification Testing	N/A
Software Validation	FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Substantial equivalence is based on the intended use and design of the ERC 2 and the predicate ERC. Both the ERC 2 and the predicate ERC have the same intended use, operating principle, scientific technology, mechanism of action and performance specifications. Non-clinical performance data shows there are no new risks identified with the ERC 2 and that the device meets the intended use and performance specifications.

Additional non-clinical tests that were performed on the predicate MAGEC System are also applicable to the ERC 2 and this submission. These include animal studies, mechanical tests on the implant, biocompatibility tests on the implant, sterility and packaging testing on the implant. These tests were not repeated since the implant component of the MAGEC System are not being changed as part of this premarket notification.

11. Clinical Performance Data: The retrospective clinical study performed on the MAGEC System and previously submitted is also applicable to the ERC 2 and this submission.

10. Conclusion: Conclusions can be drawn from the tests that the line extension to include the ERC 2 to the MAGEC System is substantially equivalent to the predicate device.